

PATENT
Attorney Docket No.: 10139-02002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)
FRIGG et al.)
Serial No.: 10/532,909) Group Art Unit: 3733
Filed: December 16, 2005) Examiner: N. Woodall
For: DEVICE FOR THE TREATMENT)
OF FRACTURES OF THE)
FEMUR)
Confirmation No. 3108)

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed on November 20, 2007, and pursuant to
37 C.F.R. § 41.37, Appellants presents this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the
Examiner's final rejection of claims 19-40 in the Final Office Action dated July 20, 2007. The
appealed claims are set forth in the attached Claims Appendix.

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1. Real Party in Interest

This application is assigned to Synthes (U.S.A.), the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1-18 have been canceled, and claims 19-40 have been rejected in the final Office Action. Claims 19-40 are the subject of this appeal.

4. Status of Amendments

All amendments submitted by the Appellant have been entered.

5. Summary of Claimed Subject Matter

The following summary refers to the specification and identifies certain claim limitations with the reference characters of one or more drawings. The association in this summary of a claim limitation with a particular reference character, figure, or passage from the specification is only exemplary and is not intended to limit the scope of the claims.

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The present invention, as exemplified in claim 19, is directed to a device for the treatment of femoral fractures that includes an intramedullary pin (1) having a first longitudinal axis (2), a proximal portion (4), a distal portion (3), and at least one transverse opening (5) through the proximal portion of the pin (1). (Specification at page 6, lines 7-10 ; Figure 1). The transverse opening (5) has a non-circular cross-section and forms an oblique angle with the first longitudinal axis (2). (Specification at page 6, lines 7-10; Figure 1). The device also includes a bone fixation element (20) having a second longitudinal axis (21); the bone fixation element has a shaft (24), an end of which is configured and dimensioned to engage bone in the femoral head. (Specification at page 6, lines 16-20; Figure 1). Another part of the device is a sliding sleeve (10). (Specification at page 6, line 2; Figure 1). The sliding sleeve (10) includes a central bore (13) that receives the shaft (24) of the bone fixation element (20) while permitting free rotation of the bone fixation element (20) relative to the sleeve (10). (Specification at page 7, lines 10-13 and lines 19-21; Figure 2). An external surface profile of the sleeve (10) has at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening (5); the mating prevents the sleeve (10) from rotating with respect to the pin (1). (Specification at page 7, lines 22-25; Figure 2). The device also includes a locking element (30) that selectively locks rotation of the bone fixation element (20) relative to the sleeve (10) when in a first position, and that permits free rotation of the bone fixation element (20) relative to the sleeve (10) when in a second position. (Specification at page 6, line 30, to page 7, line 4; Figures 1 and 6).

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The present invention, as exemplified by claim 37, is directed to a device for the treatment of femoral fractures that includes an intramedullary pin (1) and a cross member. The pin (1) includes a first longitudinal axis (2), a proximal portion (4), a distal portion (3), and at least one transverse opening (5) through the proximal portion (4), with the transverse opening (5) forming an oblique angle with the first longitudinal axis (2). (Specification at page 6, lines 7-10; Figure 1). The cross member includes a sliding sleeve (10), a bone fixation element (20), and a locking mechanism (30). (Specification at page 6, lines 1-4; Figure 1). The sliding sleeve (10) includes a central bore (13), a circular interior surface profile (see Figure 2), and a non-circular exterior surface profile (See Figure 2). (Specification at page 6, lines 11-14). The exterior surface profile of the sliding sleeve (10) mates with the non-circular profile of the transverse opening (5), thereby preventing rotation of the sleeve (10) with respect to the pin (1). (Specification at page 7, lines 22-25; Figure 2). The bone fixation element (20) includes a shaft (24) and an end (23) configured and dimensioned to engage bone in the femoral head. (Specification at page 6, lines 16-20; Figure 1). The shaft (24) is configured and dimensioned for free rotation within the central bore (13) of the sliding sleeve (10). (Specification at page 7, lines 10-13 and lines 19-21; Figure 2). The locking mechanism (30) is configured and adapted to selectively lock rotation of the bone fixation element (20) relative to the sleeve (10) when in a first position, and to permit free rotation of the bone fixation element (20) relative to the sleeve (10) when in a second position. ((Specification at page 6, line 30, to page 7, line 4; Figures 1 and 6).

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6. Ground of Rejection to be Reviewed on Appeal

I. Whether claims 19 and 37 are unpatentable under 35 U.S.C. § 103(a) over United States Patent No. 5,032,125 to Durham et al. ("Durham").

II. Whether claims 19-25, 27, 31, 34-38, and 40 are unpatentable under 35 U.S.C. § 103(a) over Durham in view of United States Patent No. 5,454,813 to Lawes ("Lawes").

III. Whether claim 27 is unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 6,648,889 to Bramlet et al. ("Bramlet").

IV. Whether claims 28 and 29 are unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 4,432,358 to Fixel ("Fixel").

V. Whether claims 30, 32, and 39 are unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 5,908,422 to Bresina ("Bresina").

VI. Whether claim 33 is unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes, Bresina, and United States Patent No. 6,187,007 to Frigg et al. ("Frigg").

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7. Argument

I. The Durham Rejection

Claims 19 and 37 recite that “the at least one transverse opening...[has] a non-circular cross-section.” Not only does the Examiner fail to address this limitation in the rejection based on Durham, but the Examiner even acknowledges in the next rejection based on Durham and Lawes that “Durham fails to disclose the transverse bore of the intramedullary pin having a non-circular cross-section (claims 19 and 37)...” Final Office Action at page 4. Having acknowledged this deficiency in Durham without showing, despite this deficiency, how Durham alone still establishes the obviousness of this limitation, the Examiner has failed to establish a prima facie case of obviousness. Accordingly, reversal of this rejection is requested.

II. The Durham-Lawes Rejection

Appellants submit that neither Durham or Lawes shows the recited “locking mechanism configured and adapted to selectively lock rotation of the bone fixing element relative to the sleeve....” The Examiner believes that compression screw 90 teaches the locking mechanism. Appellants disagree because screw 90 does nothing to lock rotation of lag screw 60 relative to sleeve 40. The rotation of screw 60 is already locked relative to sleeve 40 by the complementary surfaces 44 and 66. (Column 4, lines 3-6) (“The surfaces 44 and 66 cooperate to prevent lag screw 60 from rotating within sleeve 40.”). Since surfaces 44 and 66 lock the screw 60 relative

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to sleeve 40, attributing this function to compression screw 90 would be superfluous. Indeed, compression screw 90 performs a completely different function, namely, to "provide[] a means for cooperation with the lag screw and the sleeve for supplying sliding compressive forces to selected fractures of the femur." (Column 4, lines 29-32). Indeed, compression screw 90 is incapable of providing the rotation locking recited in the claim because compression screw 90 only engages the interior surface of bore 68 of lag screw 60. Even if sleeve 40 and lag screw 60 could not lock onto each other through surfaces 44 and 66, in other words, even if sleeve 40 had a completely cylindrical bore and lag screw had a completely cylindrical shaft, the tightening or loosening of screw 90 would not prevent or facilitate their relative rotation. The operation of screw 90 is thus irrelevant to the degree of rotation between screw 60 and sleeve 40, and is instead relevant only to the compressive force applied to the fracture.

Lawes does not overcome this deficiency in Durham. Like Durham, Lawes locks rotation of screw 7 relative to 12 through the cooperation of complementary abutment surfaces, as shown in Figures 2-5. Like screw 90 of Durham, the screw 19 of Lawes acts as a "tension adjuster for applying an adjustable tension to the neck screw [7] to urge proximal end of the neck screw [7] towards the rod [1] when the locking means provided by the sleeve have been actuated." (Column 4, lines 28-31).

Further, the Examiner has not been persuaded by Appellants' argument basing patentability on the absence in Durham of a sliding sleeve that is "configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative

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to the sleeve," as recited in claim 19. A similar limitation appears in claim 37.

Durham unquestionably lacks this feature. The Examiner does not dispute its absence. Instead, the Examiner contends that despite the absence of this limitation in Durham, one of ordinary skill in the art, at the time of the claimed invention, would have been able to arrive at the claimed invention. Specifically, the Examiner asserts that the transforming of flat surfaces 44 of the sleeve bore 42 and flat surfaces 66 of body member 62, which the Examiner does not argue can achieve the "free rotation" of the claims, into circular surfaces permitting such free rotation is well within the ability of one of ordinary skill in the art. No evidence in the form of another reference or publication is offered to support the contention that Durham could be modified so that the sleeve 40 is changed to permit the free rotation of the inserted lag screw 60. Indeed, the presence of flat surfaces 44, 66 is strong evidence that Durham teaches away from permitting such free rotation. Since the flat surfaces 44, 66, achieve precisely the opposite effect of free rotation, the contention that Durham would nevertheless have supported a modification to achieve such free rotation is suspect.

In answer to the question of why would Durham, the only evidence relied on by the Examiner to reject the free rotation aspect of the claims, have prompted one of ordinary skill in the art to make this modification is answered by the Examiner with only an unfounded rationale: since "Durham does not disclose that the prevention of rotation of the screw in the sleeve is a critical function of the device" (Final Office Action at page 8), then one of ordinary skill in the art would have recognized this modification. Under the Examiner's theory of obviousness, an

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Applicant can legitimately distinguish a reference only on the basis of those features identified explicitly in the reference as "critical." If an Applicant says that the reference does not have a particular feature, and that reference expressly identifies this feature as critical, then the Applicant should expect to receive a patent under the Examiner's view of obviousness. On the other hand, if an Applicant finds that the reference differs from the claim with respect to a particular feature that is not expressly identified as critical, which in the Examiner's mind somehow means that it is non-critical, then the Examiner is free to argue that this supposedly non-critical feature in the reference can be modified in whatever way the Examiner wishes in order to arrive at the claimed invention, even if he must completely eviscerate the purpose of the particular non-critical feature in the reference. Appellants disagree with this approach, especially since a feature of a reference can be correctly characterized as critical even if the reference does not use the word "critical" to characterize its importance. Indeed, an Examiner should not wave off any non-obviousness argument simply on the assertion that the reference on which the rejection is based fails to characterize the distinguishing feature in the reference as "critical". Even more curious is the contention, made at page 2 of the Final Office Action, that since Durham never states that the flat surfaces 44, 66 are necessary for the Durham device to operate properly, a surface with a circular cross-section could be used. Is there any authority to which the Examiner can cite that justifies such a non sequitur? What if the claim recited some oily or other slippery substance to achieve this free rotation? Would the alleged non-criticality of the flat surfaces in Durham have justified the Examiner in regarding such a substance as obvious too?

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Apparently, it would not be unfair to characterize the logical implication of the Examiner's position by stating that any conceivable way to achieve this free rotation is within the grasp of one of ordinary skill in the art. What makes this position even more untenable is that it is based on a reference that teaches the precise opposite, that teaches instead the prevention, not the facilitation, of such free rotation through the presence of complementary flat surfaces 44, 66. Appellants do not dispute that the flat surfaces 44, 66 could be modified in some way consistent with the knowledge of one of ordinary skill in the art, but any such modification to these surfaces must preserve the rotation prevention achieved by them. For instance, the flat surfaces 44, 66 could be modified into some non-flat, yet interlocking, complementary surfaces that preserve their locking ability.. On the other hand, a modification to these surfaces such as the one the Examiner proposes undermines this rotation prevention aspect of Durham solely for the purpose of meeting the claim limitation. Unless there is some pre-filing evidence that supports such a modification, the Examiner is engaging in nothing but hindsight to arrive at the claimed invention. Thus, in view of this discussion, claims 19 and 37 are patentable over Durham and Lawes.

Similarly, all the dependent claims listed in this rejection are patentable for at least the same reasons given above.

III. The Durham-Lawes-Bramlet Rejection

The Examiner incorrectly refers to claim 27 here, since the rejection addresses the limitations of claim 26. Since Bramlet does not overcome the deficiencies noted above, claim 26 is patentable for at least the same reasons given above.

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IV. The Durham-Lawes-Fixel Rejection

Since Fixel does not overcome the deficiencies noted above, claims 28 and 29 are patentable for at least the same reasons given above.

V. The Durham-Lawes-Bresina Rejection

Since Bresina does not overcome the deficiencies noted above, claims 30, 32, and 39 are patentable for at least the same reasons given above.

VI. The Durham-Lawes-Bresina-Frigg Rejection

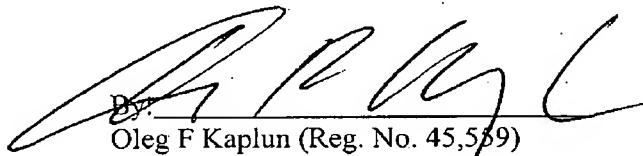
Since Frigg does not overcome the deficiencies noted above, claim 33 is patentable for at least the same reasons given above.

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8. Conclusions

For the reasons set forth above, Appellants respectfully requests that the Board reverse the final rejection of the claims by the Examiner and indicate that all pending claims are allowable.

Respectfully submitted,


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CLAIMS APPENDIX

19. (Previously presented) A device for the treatment of femoral fractures comprising:
- an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section;
 - a bone fixation element having a second longitudinal axis, a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head,
 - a sliding sleeve having a central bore, an interior surface profile, and an exterior surface profile, the central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve, and the exterior surface profile having at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening, thereby prevention rotation of the sleeve with respect to the intramedullary pin; and
 - a locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position.

20. (Previously presented) The device of claim 19, wherein the bone fixation element, sliding sleeve and locking mechanism are adapted for insertion through the transverse opening in the pin as a single preassembled unit.

21. (Previously presented) The device of claim 19, wherein the second end of the bone fixation element includes a longitudinal bore.

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22. (Previously presented) The device of claim 21, wherein the longitudinal bore at the second end of the bone fixation element is at least partially threaded.

23. (Previously presented) The device of claim 22, wherein the locking mechanism is a fixing screw having a screw head with a diameter D and a screw shank with a diameter d having an outside thread, where $D > d$.

24. (Previously presented) The device of claim 23, wherein the outside thread of the fixing screw shank corresponds to the threaded bore of the bone fixation element, and progressive tightening of the fixing screw within the threaded bore rotationally locks the bone fixation element with the sliding sleeve, thereby preventing rotation of the bone fixation element relative to the sliding sleeve.

25. (Previously presented) The device of claim 19, wherein the bone fixation element is axially fixed relative to the sliding sleeve.

26. (Previously presented) The device of claim 25, wherein the shaft of the bone fixation element includes a first annular groove and the internal surface profile of the sliding sleeve includes a second annular groove, and a ring element engages both the first and second annular grooves to prevent axial displacement of the shaft relative to the sliding sleeve.

27. (Previously presented) The device of claim 19, wherein a rear end of the sliding sleeve extends a distance x past the second end of the bone fixation element, where x is at least 0.01 mm.

28. (Previously presented) The device of claim 19, wherein the second end of the bone fixation element includes an externally threaded portion.

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29. (Previously presented) The device of claim 28, wherein the locking mechanism is a nut with an internal thread that corresponds to the externally threaded portion at the second end of the bone fixation element.

30. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a helical blade.

31. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a screw thread, a chisel, a pin, a T-section or a double T-section.

32. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a plurality of helical blades.

33. (Previously presented) The device of claim 30, wherein the helical blade has a pitch of at least 50 mm.

34. (Previously presented) The device of claim 19, wherein the locking mechanism is adapted to limit axial displacement of the sliding sleeve relative to the intramedullary pin.

35. (Previously presented) The device of claim 19, wherein the bone fixation element is a screw.

36. (Previously presented) The device of claim 19, wherein the external surface profile of the sliding sleeve includes a longitudinal projection that mates with a longitudinal recess in the transverse opening.

37. (Currently amended) A device for the treatment of femoral fractures comprising:

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an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section;

a cross-member configured for insertion through the transverse opening to engage bone in the femoral head, the cross-member including:

a sliding sleeve having a central bore, a circular interior surface profile, and a non-circular exterior surface profile, the exterior surface profile adapted to mate with the non-circular cross-section of the transverse opening, thereby preventing rotation of the sleeve with respect to the intramedullary pin,

a bone fixation element having a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head, and the shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve, and

a locking mechanism configured and adapted to selectively lock rotation of the bone fixing element relative to the sleeve when in a first position and permit free rotation of the bone fixing element relative to the sleeve when in a second position.

38. (Previously presented) The device of claim 37, wherein the cross-member is adapted for insertion through the transverse opening in the pin as a single preassembled unit.

39. (Previously presented) The device of claim 37, wherein the first end of the bone fixation element includes a helical blade.

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40. (Previously presented) The device of claim 37, wherein the bone fixation element is a screw.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.